IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.,	)	
	)	
Defendant.	)	
	)	

MERCK'S SURREPLY IN OPPOSITION TO APOTEX'S MOTION FOR LEAVE TO FILE A FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

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INTRODUCTION

Apotex's contentions ignore established standards for pleading antitrust injury. Apotex's counterclaim boils down to its assertion that "but for Merck's anti-competitive acts, Apotex would likely be able to obtain a court decision finding the patents asserted by Merck to be invalid and/or not infringed" (Counterclaim ¶116) and that Apotex "has every right to a decision on the merits." Reply at 18. But, as Merck showed in its opposition, the Hatch-Waxman Act and Federal Circuit cases interpreting the Act do not confer any "right" to a decision on the merits, and Merck's alleged conduct in giving Apotex a chance to obtain such a decision (by suing Apotex) and then taking that chance away (by covenanting not to sue and seeking dismissal) cannot establish antitrust injury. Nothing said by Apotex in its reply changes those conclusions. Apotex's claimed injury simply is not an injury of the type the antitrust laws were intended to prevent. Nor is it injury that flows from that which makes the challenged acts (allegedly) unlawful. Apotex's proposed counterclaim fails as a matter of law.

ARGUMENT

I. LEGAL STANDARD FOR AMENDMENT UNDER RULE 15(a)

A. The Court Properly Considers Facts In The Record In Exercising Its Discretion Under Rule 15(a)

Apotex contends that the Court may not consider facts that do not appear in Apotex's proposed counterclaim. Reply at 1-2, 6-7, 9, 23-24, 29, 32-33. To the contrary, the Court should not ignore the record in this case. Under Rule 15(a), "[a] district court has the discretion to deny a party's request for leave to amend if it is apparent *from the record* that [] the moving party has demonstrated . . . bad faith or . . . the amendment would be futile. . . ." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 527 (D. N.J. 2004) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Fed. Deposit Insur. Corp. v. Bathgate*, 27 F.3d 850, 874 (3rd Cir.

1994)).[1] "A district court has substantial leeway in deciding whether to grant leave to amend." *Id.* Thus, while Rule 12(b)(6) provides the standard for assessing the legal sufficiency of Apotex's pleading, Rule 15(a) adds the element of discretion. *See id.* In exercising that discretion, the Court should consider Apotex's allegations in the context of both versions of the proposed pleading, the motion to substitute, related briefs, and other undisputed facts and documents in the record. *See, e.g., Fed. Deposit Insur. Corp.*, 27 F.3d at 875 (affirming denial of leave to assert counterclaims resting on allegation contradicted by record); Merck's Opp. Br. at 34 nn.19, 20.

B. Antitrust Claims Are Not Subject To A Lower Pleading Standard

Apotex contends that under Rule 12(b)(6), "[t]he dismissal standard is even higher in antitrust cases than it is generally." Reply at 2. Apotex is wrong again: "in antitrust cases . . . the general principles governing Rule 12(b)(6) motions apply." *In re K-Dur*, 338 F. Supp. 2d at 529 ("The pleading standard in an antitrust case requires that the plaintiff plead his complaint with particularity; . . . 'conclusory recitations of law' [are] insufficient to survive a motion to dismiss.");[2] *see also* Merck's Opp. Br. at 9-11 (citing cases).

Apotex incorrectly cites three cases for its erroneous assertion that "[t]he dismissal standard is even higher in antitrust cases than it is generally." Apotex quotes *Hosp. Bldg. Co. v. Trs. of Rex Hosp.*, 425 U.S. 738, 746 (1976), for the statement that "in antitrust cases . . . dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." (Ellipse original.) But Apotex's carefully placed ellipse misleadingly omits the

[1] Unless otherwise noted, in all citations herein emphasis has been added and internal citations and quotation marks omitted. Also, Merck incorporates by reference the cited portions of its prior briefs.

[2] *See also Syncsort, Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 328 (D.N.J. 1999) ("[F]acts must be pleaded with reasonable particularity . . . to permit an inference that [an] antitrust claim is cognizable."); *Electronics Communs. Corp. v. Toshiba Am. Consumer Prods.*, 129 F.3d 240, 243 (2d Cir. 1997) ("[C]onclusory statements [cannot] substitute for minimally sufficient factual allegations.").

key limiting language: "*where the proof is largely in the hands of the alleged conspirators.*" *See id.* Apotex has not alleged any conspiracy or collusion by Merck.[3]

Apotex also purports to quote *Pennsylvania ex rel. Zimmerman v. Pepsico, Inc.*, 836 F.2d 173, 182 (3rd Cir. 1988), as holding that "[courts] should be extremely liberal in construing antitrust complaints." Reply at 2. Apotex's citation is incorrect; the quoted statement was made not by the Third Circuit in *Zimmerman*, but twenty years earlier in *Knuth v. Erie-Crawford Dairy Coop.*, 395 F.2d 420, 423 (3rd Cir. 1968), and the court in *Zimmerman* explicitly rejected it, holding "that litigation today is too expensive a process to waste time on fanciful claims: When the requisite elements are lacking, the costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint." *See Zimmerman*, 836 F.2d at 182.[4]

II. APOTEX'S PROPOSED ANTITRUST COUNTERCLAIM IS FUTILE

A. Apotex Suffers No Antitrust Injury From The 30-Month Stay

1. The 30-Month Stay Will Be Lifted Upon Entry Of Dismissal

Section 355(j)(5)(B)(iii)(I) states that the 30-month stay is lifted upon a "substantive determination that there is no cause of action for patent infringement or invalidity." Merck contends that if the Court decides that Merck's covenant not to sue requires dismissal of Apotex's original counterclaim for a declaration of patent invalidity, that will constitute a

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[3] Similarly, Apotex cites *Rolite, Inc. v. Wheelabrator Envtl. Sys., Inc.*, 958 F. Supp. 992, 995 (E.D. Pa. 1997), where the court stated: "Summary procedures should be used sparingly in complex antitrust litigation *where motive and intent play leading roles, the proof is largely in the hands of the alleged conspirators, and hostile witnesses thicken the plot*." None of these circumstances constrain Apotex's ability to plead antitrust injury, injury-in-fact, or objective baselessness under *Noerr-Pennington*.

[4] *See also Associated General Contractors, Inc. v. Calif. State Council of Carpenters*, 459 U.S. 519, 528 n.17 (1983) ("[A] district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.").

"substantive determination that there is no cause of action for patent . . . invalidity" as described in the statute. Apotex disagrees, contending a "substantive determination" means "a decision directed at the merits, either by way of summary judgment or failure to state a claim," and that Merck "fails to recognize the distinction between a court's power to a hear the case, i.e., its subject matter jurisdiction, and the merits of a case." Reply at 5. Merck does not dispute the difference between dismissal for lack of subject matter jurisdiction and dismissal on the merits, but disagrees with Apotex's unsupported conclusion that this distinction is dispositive. There is nothing in the statute that refers to a "decision on the merits" and Apotex cites no authority for its interpretation. The statute refers to a "substantive determination that there is no cause of action for patent infringement or invalidity." A determination that Merck's covenant removes any controversy between the parties is necessarily a determination that Apotex does not have a cause of action for patent invalidity against Merck (and likewise that Merck does not have a cause of action for patent infringement against Apotex).

Apotex next argues that the fact that the FDA approved Apotex's ANDA for a generic version of Zaditor® after dismissal of a patent infringement suit by pioneer drug company Novartis, but prior to the expiration of the 30-month stay imposed when Novartis filed suit, proves nothing and should not be considered. Apotex argues that since Merck contends that the interpretation of section 355(j)(5)(B)(iii)(I) is a question of law, "Merck cannot rely on factual matters," that Merck improperly creates a factual dispute as to FDA policy, and that the FDA's action "is irrelevant to the motion at hand because it is not in any pleading." Reply at 6-7. These contentions lack merit. It is true of course that the Court construes the statute as a matter of law, but in doing so the Court is permitted to take judicial notice of official FDA action and taking such notice does not create a disputed factual issue. "Matters of public

record may be considered without converting the motion to dismiss into a motion for summary judgment." *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003) (citing *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). "Courts have defined a public record to include published reports of administrative bodies." *Id.* (taking judicial notice of the FDA's Center for Drug Evaluation and Research Listing of New and Generic Drug Approvals). It is thus proper for the Court to take judicial notice of the undisputed fact of the FDA's approval for Apotex's generic version of Zaditor® and court filings evidencing the timing of that approval vis-à-vis the 30-month stay that was temporarily imposed during the pendency of Novartis's suit.

Furthermore, in determining futility and bad faith under Rule 15(a), the court considers not only the pleading, but the entire record. *In re K-Dur*, 338 F. Supp. 2d at 529; *Fed. Deposit Insur. Corp.*, 27 F.3d at 875. The FDA's approval of Apotex's ANDA following dismissal of Novartis's suit shows that no 30-month stay was imposed in that case, indicating that Apotex's alleged concern over the enforcement of a continuing 30-month stay is either disingenuous or highly speculative. In fact, Apotex's statements that the FDA's policy is uncertain, could be challenged, and could be overturned by a court (Reply at 7-8), culminating in the coy statement that "there is no guarantee that the FDA would approve ANDA applications where the … lawsuit was dismissed prior to the expiration of the 30-day stay" (*id.* at 9), constitute an admission that Apotex cannot predict whether it will face the 30-month stay upon dismissal of this suit, further demonstrating the speculativeness of its claimed injury. Surely Apotex does not contend that the Court must accept Apotex's unequivocal allegations about the 30-month stay as true when Apotex contradicts those allegations with highly equivocal statements in its

own briefing.[5]

A further peculiarity of Apotex's position is that Apotex is advocating an interpretation that would cause the very injury it claims. The reason that Apotex argues against its own apparent interest is clear: Apotex's real goal is not to avoid that purported injury, but instead to manufacture it to keep this case from being dismissed so that Apotex has a chance to obtain a triggering "court decision" to deprive first-ANDA-filer Teva of its statutorily-granted 180-day exclusivity period. Apotex takes the same tack with respect to the Court's authority to shorten the 30-month stay. The Court should reject Apotex's attempt to cause its own "injury" to mire Merck and this Court in an antitrust case where the purported injury is plainly non-existent (or, at best, highly speculative) and the true goal is to concoct jurisdiction.

2. The Court Is Authorized To Shorten The 30-Month Stay

Section 355(j)(5)(B)(iii) authorizes the court to shorten the 30-month stay to such "period as the court may order because either party to the action failed to reasonable cooperate in expediting the action." Merck contends this provision permits the Court to shorten the stay in this case; Apotex disagrees. First, Apotex contends "Merck's shortening suggestion presents issues of fact, which this Court should not consider in a 12(b)(6) motion." Reply at 9. This contention lacks merit. The scope of the Court's statutory authority to shorten the stay is a question of law. In deciding whether to exercise that authority at the juncture of a Rule 15(a) motion to amend, the Court accepts Apotex's well-pleaded allegations, but also properly takes notice of undisputed facts in the record—including Merck's offer to stipulate to shorten the stay. Apotex's contention that the Court should ignore Merck's undisputed offer shows once

[5] Apotex's knowledge that the FDA recently approved its ANDA following dismissal of patent litigation against it also is relevant to whether Apotex acted in bad faith when it alleged, contrary to its own recent experience, that the 30-month stay remains in place as a matter of law.

again that Apotex does not want to avoid the claimed injury.

Next, Apotex contends that Merck's assertion that the Court may shorten the stay "*may not be correct*" and that "*it is not known*" whether the Court has such authority under section 355(j)(5)(B)(iii). Reply at 9-10. While now apparently conceding that interpretation of the statute is a legal question, Apotex refuses to take a position on how the statute should be interpreted. Apotex wants to have it both ways: to argue that the Court "may not" have the authority to shorten the stay in this case (so that Apotex can keep the case alive), while leaving the door open for Apotex to ask this or other courts to exercise that authority in Apotex's favor in the future. Apotex's hedging further highlights the speculative nature of its claimed injury.

Apotex also cites *Dey, L.P. v. Eon Labs, Inc.*, 2005 U.S. Dist. LEXIS 39475, at *11-12 (C.D. Cal. Dec. 22, 2005), in which the district court shortened the stay in response to the defendant's contention that the plaintiff had failed to conduct an adequate pre-suit inquiry; and contrasts it with *Andrx Pharms, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002), in which the Federal Circuit held that a district court exceeded its authority in shortening the stay because the statute "is addressed only to delay related to a particular infringement action." Reply at 9-10. Apotex makes no point with this comparison; *Dey* and *Andrx* are entirely consistent,[6] and continuing to hedge, Apotex does not contend that the court in *Dey* exceeded its authority by shortening the stay based on delay resulting from the plaintiff's failure to conduct a reasonable pre-suit inquiry. *See* Reply at 9-10.

[6] In *Andrx*, the Federal Circuit found that the district court erred because it shortened the stay due to allegedly improper action before the FDA and delay in the resolution of other infringement actions, as opposed to conduct in the proceeding before it. In contrast, *Dey* involved conduct related to the pending suit – specifically, the failure to conduct a reasonable pre-suit inquiry and form a clear position on inventorship at the outset. Here, Merck's alleged failure to conduct a reasonable pre-suit inquiry and purported refusal to accept Apotex's restrictive terms for pre-suit access to its ANDA (Reply at 25-27) is conduct specifically related to this proceeding, as is the provision of the covenant not to sue.

B. Apotex Suffers No Antitrust Injury From Being Unable To Trigger The 180-Day Exclusivity Period

Merck contends that Apotex's claimed injury – deprivation of the chance to obtain a triggering decision and resultant delayed market entry – flows from the operation of Hatch-Waxman and not any alleged wrongful conduct by Merck. Apotex disagrees. Apotex contends "the Hatch-Waxman scheme does not fully account for Apotex's injury" because "Apotex would not be barred by the 180-day exclusivity period but for the fact that Merck listed patents in the Orange Book." Reply at 13. But absent allegations of fraudulent or improper listing, there is nothing anticompetitive or wrongful about Merck's listing patents in the Orange Book as required by Hatch-Waxman.[7] Apotex admits this point when, in trying to distinguish *Teva v. Pfizer* (discussed *infra*), it states the Federal Circuit "found that Teva did not suffer injury-in-fact because there was no wrongful conduct by Pfizer" since "Pfizer *merely listed its patents in the Orange Book as it was required to do*." Reply at 16.

Apotex next contends it is Merck's purported "manipulation" of the statute that causes Apotex's claimed injury. Reply at 13-14. But Apotex does not allege any facts showing "manipulation" of Hatch-Waxman by Merck. Apotex alleges only that Merck (1) listed its patents in the Orange Book as it is required to do, (2) sued Apotex for infringement in response to Apotex's ANDA as the statutory scheme anticipates,[8] and (3) provided a covenant not to sue and moved to dismiss the case as permitted by the Federal Circuit after Apotex finally revealed its confidential ANDA information. None of these alleged acts proximately caused the

[7] Compare *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1343-44 (Fed. Cir. 2003), in which Apotex alleged that patents listed in the Orange Book by pioneer drug maker SmithKline Beecham were improper because the patents do not claim any element of the pioneer drug or any method of using that drug as to which a claim of patent infringement could reasonably be asserted, as required by 21 U.S.C. § 355(c)(2). Apotex makes no such allegation against Merck.

[8] "The purpose of the forty-five day period is to provide the patentee time in which to bring a suit for patent infringement." *Warner Lambert Co. v. Purepac Pharm. Co.*, 2000 WL 34213890, at *15 (D.N.J. 2000) (citing legislative history).

imposition or extension of the 180-day exclusivity period.[9] In contrast, in each of the cases Apotex cites, the patentee's allegedly wrongful acts proximately caused the imposition or extension of the statutory bar to market entry. For example, Apotex cites *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 431 (D. Del. 2006), for the purported holding that an "allegation that generic drug company was excluded from the market for a certain drug, or delayed market entry, was adequate to allege antitrust injury." Reply at 11. But that allegation, standing alone, untethered to any alleged conduct that is a material cause of the exclusion, is not sufficient to show causation, and *Abbott Labs* did not hold otherwise.[10] Instead, the court found that the defendant sufficiently alleged manipulation of Hatch-Waxman based on allegations, *inter alia*, that plaintiff responded to the threat of generic entry by twice changing the formulation of its pioneer drug not to improve the product but simply to prevent generic substitution and force generic companies to file multiple ANDA applications and defend multiple suits. *See Abbott Labs*, 432 F. Supp. 2d at 415-18, 431-32.

Similarly, Apotex cites *Warner Lambert Co. v. Purepac Pharm. Co.*, 2000 WL 34213890, at *8 (D.N.J. 2000), for the purported holding that a "pioneer manufacturer's institution of suit against generic manufacturer, which thereby delayed approval of generic form and hence delayed generic entry into the market, was sufficient causation to allege antitrust injury." Reply at 12. Apotex misrepresents the holding by omitting key facts. In

[9] Prior to Merck's suit, Apotex was barred from entering the market before the expiration of first-ANDA-filer Teva's 180-day exclusivity period and lacked the opportunity to obtain a decision that Merck's patents are invalid or not infringed (and thus usurp that exclusivity period) absent a reasonable apprehension of suit by Merck. Upon dismissal of this suit due to Merck's covenant, Apotex will face the same 180-day exclusivity bar and the same inability to obtain a triggering decision.

[10] Apotex also cites *Abbott Labs* to support Apotex's statement that "it is well-established that exclusion of a competitor from a market constitutes antitrust injury." Reply at 11. This overbroad statement is incorrect and misses the point; the exclusion must be proximately caused by the alleged anticompetitive conduct and not the statutory scheme.

Warner Lambert, the generic alleged that the pioneer had fraudulently listed certain patents in its NDA even though those patents were not used at any point during the production of the drug, thereby forcing the FDA to list those patents in the Orange Book and permitting the pioneer to sue the generic for infringement, resulting in the imposition of a 30-month stay. 2000 WL 34213890, at *3. The trial court found that the FDA's decision to delay approval of the ANDA "was not left to the discretion of the FDA, so it cannot be attributed to the structure of the regulated industry," but rather was proximately caused by the pioneer's fraudulent act of improperly listing the patents in its NDA. *Id.* at *8.

Apotex also cites three cases – *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004), *Andrx Pharms, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), and *In re Cardizem Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) – which distinguish *City of Pittsburgh v. West Penn Power*, 147 F.3d 256 (3d Cir.1998), the case (among others) that Merck cited for the principle that market exclusion resulting from a regulatory scheme cannot constitute antitrust injury. Reply at 12-13. Each of the cases cited by Apotex shows why the principle articulated in *City of Pittsburgh* did not apply in those cases but does apply here: the alleged anticompetitive conduct – collusive agreements between pioneer and generic companies – caused an extension of the statutory bar resulting from the 180-day exclusivity period.[11]

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[11] In *K-Dur*, the court found that defendants' alleged collusive agreement, and not merely Hatch-Waxman, caused the claimed injury. 338 F. Supp. 2d at 534-35 ("If the 180-day period is manipulated or abused through an agreement between the brand and generic manufacturers, then this will cause injury to flow from the agreement.").

Similarly, in *Andrx*, the D.C. Circuit's reversal of the district court's finding of no antitrust injury rested on the alleged collusive agreement. *See* 256 F.3d at 810 ("Although the 180-day provision of the Hatch-Waxman Act legally barred [the second generic] from selling its product, [the first generic's] manipulation of the exclusivity trigger date extended the legal bar.").

The court in *In re Cardizem* came to the same conclusion: "Unlike . . . in *City of Pittsburgh* . . . Plaintiffs here allege an antitrust injury – having to pay an artificially high price – that flows directly from the alleged antitrust violation . . . . The Hatch-Waxman Amendments did not prohibit Andrx from going to market with its generic product. . . . [Plaintiffs] alleged that but for HMRI's promise to

Applying the appropriate standard under Rule 15(a), it is clear that while the pendency of Merck's suit causes the temporary imposition of a 30-month stay, Merck did not delay Apotex's potential market entry through any alleged manipulation of the regulatory scheme. Apotex argues that Merck is manipulating the scheme by depriving Apotex of the opportunity to obtain a triggering court decision that would allow Apotex to usurp Teva's 180-day exclusivity period. But Merck's allegedly sham litigation is not the cause of the deprivation of Apotex's chance in court. Absent Merck's suit or a reasonable apprehension of suit, Apotex has no justiciable controversy in which it might obtain a triggering decision.[12] Thus, Apotex's real complaint is not that Merck gave Apotex the chance for a triggering decision (by filing the allegedly sham suit), but rather that Merck then took that chance away (by providing the allegedly sham covenant not to sue). Apotex's loss of a *chance* to obtain a triggering decision thus flows not from Merck's alleged conduct but from the reality of law that, under the Hatch-Waxman Act, Article III and Federal Circuit precedent, *Apotex has no "right" to that chance*. *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332-38 (Fed. Cir. 2005); *see also* Merck Opp. Br. at 22-29.

Apotex attempts to distinguish *Teva* by arguing that "there was no wrongful conduct by Pfizer . . . . Pfizer did not sue Teva; nor did it attempt to dismiss the case based on a covenant not to sue Teva." Reply at 16. But as stated above, the allegedly sham suit and covenant are

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pay [Andrx] tens of millions of dollars to delay, Andrx would have gone to market . . . . Even though the Hatch-Waxman Amendments may authorize very specific unilateral conduct and a specific, limited restraint of trade, they do not authorize agreements to restrain trade."

[12] *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1336-37 (Fed. Cir. 2005) (holding that Congress did not intend the Hatch-Waxman Act to change the requirement that generics have reasonable apprehension of suit to create a justiciable controversy for a declaratory judgment action against the pioneer); *Mylan Pharms. Inc. v. Merck & Co.*, 2005 U.S. Dist. LEXIS 29160, *12-13 (M.D. Pa. Oct. 28, 2005) (holding that a pioneer's listing in Orange Book, its history of enforcing patents and its refusal to covenant not to sue were insufficient to establish reasonable apprehension of suit by ANDA applicant).

not a proximate cause of Apotex's claimed injury. Moreover, while Apotex has alleged that Merck's covenant is a "sham," Apotex has not alleged any facts to show that the covenant is not legally binding on Merck or that it does not fully deprive Merck of any cause of action for infringement of the patents in suit by Apotex. Indeed, Apotex has not alleged that despite the covenant, it has a reasonable apprehension of suit, but quite the opposite: Apotex alleges that Merck is attempting to avoid a patent infringement suit with Apotex.

Finally, Apotex contends that it "is not required by the Hatch-Waxman Act to wait for the company that was the first to file a paragraph IV certification to begin selling its generic product, as Merck contends," because there "is nothing in the Hatch-Waxman scheme that prohibits a secondary generic from triggering the 180-day exclusivity period prior to when the first generic filer(s) is able to enter the market." Reply at 17.[13] This is a strawman that misses the point. Congress did not "prohibit" a secondary generic from triggering the 180-day exclusivity period, but neither did Congress create a new cause of action for secondary generics to do so. *Teva*, 395 F.3d at 1332-38. Of course a secondary generic may be able to trigger the 180-day exclusivity period, but only from a court vested with Article III jurisdiction. *Id.* at 1336-37; *Mylan Pharms.*, 2005 U.S. Dist. LEXIS 29160, at *12-13.

Apotex cites *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.C. Cir. 1998), stating the court in that case "suggest[s] use of declaratory judgment action as means for subsequent ANDA applicant to trigger exclusivity period." It is true that the D.C. Circuit made that "suggestion"—but it was rejected by the Federal Circuit seven years later in *Teva*, which held that an ANDA applicant has no reasonable apprehension of suit under such circumstances

[13] *See also* Apotex's Reply at 17-18 ("If Congress wanted to protect the first generic filer's 180-day exclusivity period from being triggered in a different action before the first generic could utilize the exclusivity period, it certainly could have amended the statute to do just that.").

and thus no cause of action to obtain a triggering court decision. 395 F.3d at 1336-38. Consequently, Apotex's bald assertion that "Apotex has *every right* to a decision on the merits that, if in Apotex's favor, would constitute a triggering event of the first generic filer's 180-day exclusivity period" (Reply at 18) is plainly wrong. Apotex has *no right* to a cause of action for patent invalidity or noninfringement. Congress could have created a cause of action for generic companies to obtain a triggering decision where a patent is listed in the Orange Book, a paragraph VI certification is filed and the patentee does not sue or create a reasonable apprehension of suit, but Congress expressly declined to do so. *See id.*; *Mylan Pharms*, 2005 U.S. Dist. LEXIS 29160, at *12-13.[14]

C. Apotex Cannot Establish Injury-In-Fact

Apotex's contention that its injury is not speculative is belied by its own statements. Apotex has admitted that it does know whether the 30-month stay would be lifted upon dismissal of this suit based on Merck's covenant not to sue. Reply at 7-9. Furthermore, Apotex relies on the bald statement that it "would have obtained" a court decision finding the patents invalid or not infringed had Merck not provided the covenant not to sue. This is plainly speculative too; Apotex alleges no facts suggesting it could prove that every one of Merck's eight presumptively valid patents is invalid or not infringed, let alone facts suggesting that it could do so before February 6, 2008, when Merck's '077 patent exclusivity expires. Claimed injury based on predicting the outcome of a lawsuit is too speculative to support standing under Article III. *Whitmore v. Arkansas*, 495 U.S. 149, 159-160 (1990); Merck Opp. Br. at 30-32.

Apotex's response is to argue that since it also seeks injunctive relief, it need only

[14] The version of the Hatch-Waxman Act originally introduced in the Senate provided for jurisdiction under the Declaratory Judgment Act under such circumstances; however, this language was not included in the legislation as adopted, and the conference committee report stated that Congress did not intend for the Act to cause courts to alter the Federal Circuit's "reasonable apprehension" standard for establishing Article III jurisdiction. *Teva*, 395 F.3d at 1336-37.

allege facts showing the *threat* of antitrust injury. Reply at 19. Apotex's request for injunctive relief cannot save its inadequate pleading. An injunction may issue under section 16 of the Clayton Act only if the claimant "demonstrate[s] a *significant threat* of injury from an *impending* violation of the antitrust laws." *City of Pittsburgh*, 147 F.3d at 265. In an effort to show such a threat, Apotex argues outside of its pleadings that Merck is possibly engaged, or might in the future engage, in action to delay Teva's market entry, thereby delaying Apotex. Reply at 19. The "possible scenarios" that Apotex describes (*id.* n.9) to show this purported threat of injury – predicting theoretical future events in *separate litigation and administrative proceedings* between Merck and Teva – are gross speculation. Apotex does not allege a present threat of a real injury, but only speculation about possible ways in which its market entry could be delayed in the future, depending on a series of speculative events that might or might not happen. "It is not . . . proper to assume that [a plaintiff] can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged." *Associated Gen. Contractors*, 459 U.S. at 526.

Furthermore, if Apotex prevails, there will be nothing to enjoin for which Apotex may seek an injunction. According to Apotex, Merck already "pulled the trigger": Merck sued Apotex allegedly to impose a 30-month stay and then provided a covenant not to sue Apotex allegedly to deprive Apotex of its purported "right" to a triggering court decision to usurp the 180-day exclusivity period. If the Court allows the counterclaim for non-infringement and invalidity to go forward and Apotex obtains a triggering decision, there will be no "impending violation" to enjoin; Apotex's entry will not be delayed by any 30-month stay or 180-day exclusivity period.[15] Consequently, all that will remain of Apotex's injunction request will be

[15] *See In re Wellbutrin SR Antitrust Litig.*, 2006 U.S. Dist. LEXIS 9687, at *37 (E.D. Pa. 2006) ("Now

to enjoin theoretical future acts by Merck affecting "other secondary generics."[16] Of course, those "other secondary generics" are Apotex's potential competitors; their market entry would erode Apotex's prices. *See* Proposed Counterclaim ¶¶ 88-99. Apotex, however, lacks standing to seek an injunction to prevent injury to its potential competitors. First, it lacks Article III standing to seek to enjoin conduct that would not harm it. Second, it lacks standing under the Clayton Act to seek an injunction for the benefit of its competitors, because Apotex could not recover damages for injury to its competitors. *See Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 112 (1986) (§ 16 affords private plaintiffs injunctive relief only for those injuries cognizable under § 4). Third, since Apotex stands to benefit if the conduct directed to its competitors is not enjoined, Apotex cannot show antitrust injury for this reason too. *See Atl. Richfield Co. v. United States Petroleum Co.*, 495 U.S. 328, 336-37 (1990) (plaintiff suffers no antitrust injury from conduct that, although potentially anticompetitive, benefits plaintiff). Thus, Apotex's effort to keep its antitrust claim alive on the premise that the Court should protect Apotex's potential competitors should be rejected.

D. Apotex Has Not Alleged Facts Sufficient To Overcome Merck's *Noerr-Pennington* Immunity

In its opposition brief, Merck set forth authorities establishing that a patentee has the right to enforce its presumptively valid patents and need not accept an alleged infringer's contentions that the patents are invalid or not infringed; and thus that where an accused infringer refuses to reveal information about the accused product to allow the patentee to assess infringement, the patentee may file suit without further inquiry. *See* Merck Opp. Br. at 33, 35

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that all the infringement suits have terminated in the generic companies' favor, there is no unlawful conduct to enjoin. Accordingly, [plaintiffs] have failed to allege a claim cognizable under §16 of the Clayton Act."); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 274 (D. Mass. 2004) (plaintiffs not entitled to injunctive relief for antitrust claim based on frivolous lawsuits where the suits had already been resolved since "it is difficult to imagine how [the alleged] violation might recur").

[16] *See, e.g.*, SAC ¶¶ 96-97 , 115-16 (alleging threat of injury to "other secondary generics").

(citing, *inter alia*, *Hoffman La Roche v. Invamed, Inc.*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000) and *First Graphics, Inc. v. M.E.P. Cad, Inc.*, 2002 U.S. Dist. LEXIS 14194, at *8 (N.D. Ill. Aug. 13, 2002)). Apotex attempts to distinguish these cases by arguing that they are not antitrust or Hatch-Waxman cases and do not address whether allegations of sham litigation are sufficient under Rule 12(b)(6). Reply at 27-28. Those distinctions are irrelevant to the points for which Merck cited those cases, and Apotex fails to offer any contrary authority.

Merck also set forth authorities establishing that Apotex's arguments for why Merck's suit allegedly was objectively baseless violate basic patent law principles and require the Court to draw inferences that are unreasonable as a matter of law. *See* Merck Opp. Br. at 36-38. Apotex fails to respond to these arguments in any way. *See* Reply at 23-24, 29-32. Instead, it continues to wrongly insist that its conclusory allegations of ***subjective*** knowledge and intent are sufficient to plead ***objective*** baselessness. ***See id.*** Objective baselessness, however, means a lack of probable cause, where probable cause requires no more than an objectively reasonable belief that "there is a chance that a claim may be held valid upon adjudication." *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); *see also Eastern R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) (objective baselessness requires showing that "no reasonable litigant could realistically expect success on the merits"). While Apotex argues it has sufficiently alleged objective baselessness because Merck allegedly "knew prior to filing … suit against Apotex that Merck had no objectively reasonable basis for believing that Apotex was infringing any valid claims of [Merck's] patents," "had no reason to question Apotex's assertion that its generic would not infringe" and "only filed suit to keep Apotex out of the market for as long as possible" (Reply at 24, 30-32), these conclusory allegations of Merck's subjective state of

mind are not sufficient to plead *objective* baselessness. *See* Merck's Opp Br. at 32-38; Merck's Opp. to Apotex's Mot. to Subs. at 9-14.

Further, Apotex takes no issue with the law set forth by Merck that patent litigation will not be considered a sham so long as a "reasonable litigant" could believe that "at least one claim in the lawsuit has objective merit." *Dentsply Int'l v. New Tech. Co.*, 1996 U.S. Dist. LEXIS 19846, at *7-9 (D. Del. Dec. 19, 1996). Instead, it resorts to arguing that "Merck had no reason to question Apotex's assertions that its generic version did not infringe" any of Merck's patents. Reply at 30. Apotex thus asks the Court to infer that an objectively reasonable litigant – without seeing the FDA-filed ANDA and related documentation evidencing the composition of Apotex's potentially infringing product (as requested pre-suit) – would have accepted blanket representations from Apotex that none of Merck's eight presumptively valid patents were valid or infringed, simply because two claims of another patent had been held invalid and Apotex expressed its belief in a letter that its proposed product would not infringe any of Merck's patents. *See* Reply at 31-32. That is not a reasonable inference, nor is it sufficient to plead objective baselessness. *See* Merck's Opp Br. at 32; Merck's Opp. to Apotex's Mot. to Subs. at 9-11.

CONCLUSION

Merck respectfully requests that the Court deny Apotex's motion for leave to amend.

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Dated: December 21, 2006
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CERTIFICATE OF SERVICE

I hereby certify that on December 21, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on December 21, 2006 upon the following individuals in the manner indicated:

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